REMARKS

This document is filed in reply to the office action dated August 26, 2003 ("Office Action"). Applicants have amended the specification to update the status of one parent application, U.S. Application Serial No. 09/169,196. No new matter has been introduced.

Claims 1-3, 6-11, and 14-17 are pending. Reconsideration of this application is requested in view of the following remarks:

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected all pending claims for lack of adequate enablement. See the Office Action, page 2, lines 12-13. Applicants disagree and will discuss independent claims 1 and 9 first.

Claim 1 covers an antigen-detecting device, which contains, among others, a cell having antibodies that are expressed on the surface of the cell and are specific for an antigen to be detected. Binding of the antigen to the antibodies leads to an increase in the cytosol calcium concentration. The cell further contains an emitter molecule which, in response to the increased calcium concentration, emits a photon.

It is the Examiner's position that the specification "only teaches B-cells and fibroblasts as examples of the cells that can be used in the claimed device" and "fails to teach any other cells that can be used... " He therefore concluded that undue experimentation would be required to use any other cells. See the Office Action at page 4, lines 6-9 and lines 14-18. Applicants disagree.

The cell recited in claim 1 is required to have (1) specific cell-surface antibodies; (2) signal transduction machinery that, upon binding of an antigen to the cell-surface antibody, increases the cytosol calcium concentration; and (3) an emitter molecule which emits a photon in response to the increased calcium concentration. See claim 1 and page 3, lines 12-14 of the specification. Both the specification and the art provide ample teachings as to how to make a cell having these three elements:

First, the specification teaches that one can use genetic engineering techniques to express specific surface-bound antibodies in cells. See, e.g., page 3, lines 15-24. Further, it is well known in the art to express an antibody in cells in addition to B-cells and fibroblasts. See Tonegawa et al., Proc. Natl. Acad. Sci. U S A. 1977, 74(8): 3518-22; Kuwana et al., Biochem Biophys Res Commun. 1987, 149(3): 960-8; Davis et al., Biotechnology, 1991, 9(2): 165-9; Muller et al., Immunology Letters, 1995, 44: 97-104; Fecker et al., Plant Mol Biol. 1996, 32(5): 979-86. (attached hereto as Exhibits A-E). These references teach how to express antibodies in bacterial cells, yeast cells, plant cells, and mammalian cells (e.g., T cells and epithelial cells).

Second, it is well known in the art that various cells have signal transduction machinery for increasing the cytosol calcium concentration in response to binding of an antigen to a cell-surface antibody. Examples of such cells include pancreas cells, liver cells, muscle cells, mast cells, and sea urchin eggs. See page 899 of Molecular Cell Biology (3rd ed, by Lodish, 1995, Scientific American Books, NY, attached hereto as Exhibit F). The specification also teaches how to introduce such transduction machinery into cells that do not have it. See the paragraph bridging pages 3 and 4.

Finally, the specification teaches several emitter molecules. They can be introduced into cells by methods well known in the art. See page 6, lines 5-24.

In view of above remarks, Applicants submit that a skilled person could obtain various types of cells for the device of claim 1 via routine procedures and that no undue experimentation is required. Thus, there is no need to disclose all operative cells.

In this connection, Applicants would like to bring to the Examiner's attention that it is not necessary to disclose all species covered by claim 1 to show its operativeness. The law does not impose such a formidable burden on inventors seeking patent protection. "Appellants (here, Applicants) are not required to disclose every species encompassed by their claims even in an unpredictable art" (emphasis original). *In re Angstadt*, 190 USPQ 214, 218 (CCPA 1976). Such a holding is only reasonable, since it is very difficult, if not impossible, to test and disclose all operative species in the chemical and biotechnology fields. As further pointed out by the *Angstadt* court "[w]ithout undue experimentation or effort or expense the combinations which do

not work will readily be discovered and, of course, nobody will use them and the claims do no cover them." Id, at 219. Indeed, limiting claim 1 to only B-cells and fibroblasts would lead to an unjust result: Others could get around claim 1 by using other cells that have the above-described cell-surface antibodies, signal transduction machinery, and emitter molecules, thereby avoiding infringement.

For the reasons set forth above, Applicants submit that both the specification and the prior art adequately enable a skilled person to make and use the device of claim 1. Claim 9 coves a device for detecting the presence of multiple antigens. It has an array containing a plurality of sectors, each sector containing a cell identical to that recited in claim 1. This claim is therefore also enabled. By the same token, so are the other rejected claims, all of which depend from claims 1 and 9.

Double patenting

The Examiner rejected claims 1-3 and 6-8, under the judicially created doctrine of obviousness-type double patenting, on the ground that they are unpatentable over claims 1-8 of U.S. Patent No. 6,087,114. He also rejected claims 1-3, 6-11, and 14-17 relying on claims 1-11 of U.S. Patent No. 6,248,542 under the same doctrine. See the Office Action, page 6, lines 6-7 and page 7, lines 1-2.

In the sole interest of moving this application toward allowance, Applicants have submitted herewith a terminal disclaimer[1] and request that the rejection be withdrawn.

[1] Applicants have also submitted herewith a copy of two assignments. One assignment was executed by Todd Rider, the sole inventor named in U.S. Patent No. 6,087,114. The other was executed by Todd Rider and Laura Smith, the two inventors named in U.S. Patent No. 6,248,542.

CONCLUSION

Applicants submit that the ground for rejection asserted by the Examiner has been overcome, and that claims, as pending, define subject matter that is enabled. On this basis, it is submitted that all claims are now in condition for allowance, an action of which is requested.

Enclosed is a $205 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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